

Message

From: Pachkowski, Brian [Pachkowski.Brian@epa.gov]
Sent: 6/25/2013 5:26:09 PM
To: Kraft, Andrew [Kraft.Andrew@epa.gov]
CC: Glenn, Barbara [Glenn.Barbara@epa.gov]
Subject: Cancer MOA comments
Attachments: Cancer MOA sections - BFP 25June.docx

Attached are my comments for the mode of action sections for the upper respiratory tract and LHP cancers.

Since I perceive that these two MOA sections will receive much scrutiny from stakeholders, I attempted to be rather critical and some of my comments are admittedly nitpicky. I hope you all consider the comments carefully because I interpreted some of the studies very differently.

Ex. 5 Deliberative Process (DP)

Please note that I cut out the relevant sections from the draft Barbara emailed on 6/18 (FormaldehydeTRdraft061813incorpTechEditandDR_clean.docx). My changes are in track changes.

I would be glad to meet and discuss my comments this afternoon or prior to 2:30 on 6/26.

From: Kraft, Andrew
Sent: Wednesday, June 19, 2013 8:02 AM
To: Kraft, Andrew; Pachkowski, Brian
Cc: Vulimiri, Suryanarayana; Sonawane, Bob; Glenn, Barbara; Adams, Lynn
Subject: RE: Short-term respiratory pathology studies

Brian,

After consultation with Bob, it would also be great if you could look at the cancer MOA sections (give it a “new set of eyes”)when you receive the compiled document.

Thanks,

Andrew

From: Kraft, Andrew
Sent: Tuesday, June 18, 2013 4:56 PM
To: Pachkowski, Brian
Cc: Vulimiri, Suryanarayana; Sonawane, Bob; Subramaniam, Ravi; Glenn, Barbara
Subject: RE: Short-term respiratory pathology studies

Thank you, Brian.

As we discussed, Barbara will be sending you the most recent version of the animal nasal cancer dose-response section for review today (within the larger tox review document).

Please take as much time as you need and provide your opinion regarding clarity, flow, and content.

Thanks again,

Andrew

From: Pachkowski, Brian
Sent: Tuesday, June 18, 2013 4:43 PM
To: Kraft, Andrew
Cc: Whalan, John
Subject: Short-term respiratory pathology studies

Well, I don't think the section got longer.

Having gone through the respiratory pathology section, I don't think it was entirely possible to summarize the entire short-term dataset into 1 or 2 sentences. Some of these studies do provide unique information beyond that gleaned from the typical short-term rodent studies. I retained text regarding such unique studies. For example:

Ex. 5 Deliberative Process (DP)

Where possible, I truncated the text for the short-term pathology studies or removed it entirely and replaced it with a sentence or two summarizing such results. I took the same approach for truncating short-term (<10 weeks of exposure) cell proliferation studies. That said, below you will find a list of cell proliferation studies that only reported short-term data, which could also go into the Appendix with the short-term pathology studies.

In the attached document are only parts of the respiratory pathology section that I edited, as opposed to copying the whole behemoth of a section. I did, however, include all of the subheadings in order to provide you some reference as to where the attached text should be inserted into the current draft of the Tox Review. Let me know if you have questions about this. All of my changes are in track changes.

Short term cell proliferation studies (order reflects occurrence in evidence tables) which could go into the Appendix

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